

Sir:

PATENT Customer No. 22,852 Attorney Docket No. 08702.0093-00000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

) Group Art Unit: 1645
) Examiner: Not Yet Assigned
)) Confirmation No.: 2405)

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), Applicants bring to the attention of the Examiner the documents listed on the attached PTO 1449. This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits for the above-referenced application.

Copies of the listed documents are attached.

Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the

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documents as prior art against any claim in the application and Applicants determine that the cited documents do not constitute "prior art" under United States law, Applicants reserve the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Dated: <u>July 19, 2004</u>

Mary K. Fergusor Reg. No. 51,675



Atty. Docket No	093-00000	Appln. No. 10/689,677	
Applicant	WOLFMAN et al.		
Filing Date	October 22, 2003	Group: 1645	

U.S. PATENT DOCUMENTS						
Examiner Initial*	Document Number	Issue Date	Name	Class	Sub Class	Filing Date If Appropriate
	5,639,638	06/17/1997	Wozney et al.	435	69.4	05/20/1994
	6,437,111 B11	08/20/2002	Wozney et al.	536	23.4	08/28/1997

FOREIGN PATENT DOCUMENTS						
	Document Number	Publication Date	Country	Class	Sub Class	Translation Yes or No
	WO 94/21681	29 Sept 1994	PCT	C07K	13/00	
	WO 99/56768	11 Nov 1999	PCT	A61K	38/18	
	WO 00/43781	27 July 2000	PCT	G01N	33/50	
	WO 03/027248	03 Apr 2003	PCT x	C12N		
	WO 03/037248	08 May 2003	PCT	A61K		

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
Alexander et al., "Human Parathyroid Hormone 1-34 Reverses Bone Loss In Ovariectomized Mice," <i>J. Bone Min. Res.</i> , 16:1665-1673 (2001)
Andersson et al., "Repeated <i>In Vivo</i> Determinations of Bone Mineral Density During Parathyroid Hormone Treatment in Ovariectomized Mice," <i>J. Endocrinol.</i> , 170:529-537 (2001)
Ashmore et al., "Comparative Aspects of Muscle Fiber Types in Fetuses of the Normal and "Double-Muscled" Cattle," <i>Growth</i> , 38:501-506 (1974)

The PTO did not receive the following listed Item(s) 3/027248

INFORMATION DISCLOSURE CITATION

Atty. Docket No.	08702.0093-00000 Appln. No. 10/689,677			
Applicant	WOLFMAN et al.			
Filing Date	October 22, 2003	Group:	1645	

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	Attisano et al., "Activation of Signalling by the Activin Receptor Complex," Mol. Cell Biol., 16:1066-1073 (1996)
	Bogdanovich et al., "Functional Improvement of Dystrophic Muscle by Myostatin Blockade," Nature, 420:418-421 (2002)
	Gamer et al., "A Novel BMP Expressed in Developing Mouse Limb, Spinal Cord, and Tail Bud Is a Potent Mesoderm Inducer in <i>Xenopus</i> Embryos," <i>Dev. Biol.</i> , 208:222-232 (1999)
•	Gonzalez-Cadavid et al., "Organization of the Human Myostatin Gene and Expression in Healthy Men and HIV-Infected Men With Muscle Wasting," PNAS, 95:14938-14943 (1998)
	Hamrick et al., "Femoral Morphology and Cross-Sectional Geometry of Adult Myostatin-Deficient Mice," <i>Bone</i> , 27:343-349 (2000)
	Hill et al., "The Myostatin Propeptide and the Follistatin-Related Gene are Inhibitory Binding Proteins of Myostatin in Normal Serum," <i>J. Biol. Chem.</i> , 277:40735-40741 (2002)
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	Hoodless et al., "Mechanisms and Function of Signaling by the TGFβ Superfamily," Curr. Topics Microbiol. Immunol., 228:236-272 (1998)
	Kambadur et al., "Mutations in <i>Myostatin</i> (GDF8) In Double-Muscled Belgian Blue and Piedmontese Cattle," <i>Genome Res.</i> , 7:910-915 (1997)
	Kim et al., "Inhibition of Preadipocyte Differentiation by Myostatin Treatment in 3T3-L1 Cultures," Biochem. Biophys. Res. Comm., 281:902-906 (2001)
	Kingsley, D.M., "The TGF-β Superfamily: New Members, New Receptors, and New Genetic Tests of Function in Different Organisms," <i>Genes & Devel.</i> , 8:133-146 (1994)
· · · · · · · · · · · · · · · · · · ·	Lee et al., "Regulation of Myostatin Activity and Muscle Growth," PNAS, 98:9306-9311 (2001)
	Massagué, J., "How Cells Read TGF- β Signals," Mol. Cell Biol., 1:169-178 (2000)
	McPherron et al., "Regulation of Skeletal Muscle Mass in Mice by a New TGF- β Superfamily Member," <i>Nature</i> , 387:83-90 (1997)
	McPherron et al., "Double Muscling in Cattle Due to Mutations in the Myostatin Gene," PNAS 94:12457-12461 (1997)
	McPherron et al., "Suppression of Body Fat Accumulation in Myostatin-Deficient Mice," <i>J. Clin. Invest.</i> , 109:595-601 (2002)
	Moustakas et al., "Smad Regulation in TGF- β Signal Transduction," J. Cell Sci., 114:4359-4369 (2001)
	Nakashima et al., "Expression of Growth/Differentiation Factor 11, A New Member of the BMP/TGF\$\beta\$ Superfamily During Mouse Embryogenesis," Mech. Dev., 80:185-189 (1999)

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
R&D Systems, Inc., "Recombinant Human Activin Receptor IIB/Fc Chimera: Specifications and Use," Cat. No. 339-RB (2002)
Swatland et al., "Fetal Development of the Double Muscled Condition in Cattle," <i>J. Animal Sci.</i> , 38:752-757 (1974)
Thies et al., "GDF-8 Propeptide Binds to GDF-8 and Antagonizes Biological Activity by Inhibiting GDF-8 Receptor Binding," <i>Growth Factors</i> , 18:251-259 (2001)
Wagner et al., "Loss of Myostatin Attenuates Severity of Muscular Dystrophy in <i>mdx</i> Mice," <i>Ann. Neurol.</i> , 52:832-836 (2002)
Whittemore et al., "Inhibition of Myostatin in Adult Mice Increases Skeletal Muscle Mass and Strength," <i>Biochem. Biophys. Res. Comm.</i> , 300: 965-971 (2003)
Wuytens et al., "Identification of Two Amino Acids in Activin A That Are Important for Biological Activity and Binding to the Activin Type II Receptors," <i>J. Biol. Chem.</i> , 274:9821-9827 (1999)
Zimmers et al., "Induction of Cachexia in Mice by Systematically Administered Myostatin," <i>Science</i> , 296:1486-1488 (2002)

Examiner Date Considered		Date Considered		
*Examiner:	niner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			
Form PTO 1449		Patent and Trademark Office - U.S. Department of Commerce		